HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 451 Non-Opioid Directives
SPONSOR(S): Plakon
TIED BILLS: **IDEN./SIM. BILLS:** SB 630

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Substance abuse affects millions of people in the U.S. each year. Drug overdoses have steadily increased and now represent the leading cause of accidental death in the U.S., the majority of which involve an opioid. In Florida, opioids (licit and illicit) were responsible for more than 5,000 deaths in 2017. The National Institute on Health reports that the majority of heroin users first misused a prescription opioid.

HB 451 directs the Department of Health to develop and post on its website a voluntary non-opioid directive form. The non-opioid directive's purpose is to notify certain health care practitioners that the patient may not be prescribed, ordered, or administered an opioid. Those practitioners who exercise reasonable care and refuse to dispense, order, or administer an opioid to a patient in compliance with a voluntary non-opioid directive, may not be held civilly or criminally liable, and may not be deemed to have violated the standard of care. However, a health care practitioner may be subject to licensure discipline if he or she fails to honor the voluntary non-opioid directive.

The bill also authorizes a patient to designate a guardian or health care surrogate who may revoke the voluntary non-opioid directive, in writing or verbally, at any time, for any reason. The bill provides civil and criminal immunity for a guardian or health care surrogate who, in good faith, revokes a voluntary non-opioid directive.

Certain health care providers who dispense, prescribe, order, or administer an opioid to patients who have executed a voluntary non-opioid directive are protected from civil action or criminal prosecution and deemed not to have violated the standards of care if they exercise reasonable care.

The bill has a non-recurring, insignificant negative fiscal impact on the Department of Health, which current resources are adequate to absorb. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2019.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Substance Abuse

Substance abuse refers to the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs.[1] Substance abuse disorders occur when the chronic use of alcohol or drugs causes significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.[2] Repeated drug use leads to changes in the brain's structure and function that can make a person more susceptible to developing a substance abuse disorder.[3] Brain imaging studies of persons with substance abuse disorders show physical changes in areas of the brain that are critical to judgment, decision making, learning and memory, and behavior control.[4]

According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, a diagnosis of substance abuse disorder is based on evidence of impaired control, social impairment, risky use, and pharmacological criteria.[5] The most common substance abuse disorders in the United States are from the use of alcohol, tobacco, cannabis, stimulants, hallucinogens, and opioids.[6]

Opioid Abuse

Opioids are psychoactive substances derived from the opium poppy, or their synthetic analogues.[7] They are commonly used as pain relievers to treat acute and chronic pain. An individual experiences pain as a result of a series of electrical and chemical exchanges among his or her peripheral nerves, spinal cord, and brain.[8] Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves.[9] When an individual experiences pain, the body releases hormones, such as endorphins, which bind with targeted opioid receptors.[10] This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.[11] Opioids function in the same way by binding to specific opioid receptors in the brain, spinal cord, and gastrointestinal tract, thereby reducing the perception of pain.[12] Opioids include[13]:

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[1] World Health Organization, *Substance Abuse*, available at http://www.who.int/topics/substance_abuse/en/ (last visited March 2, 2019).
[2] Substance Abuse and Mental Health Services Administration, *Substance Use Disorders,* available at http://www.samhsa.gov/disorders/substance-use (last visited March 2, 2019).
[3] National Institute on Drug Abuse*, Drugs, Brains, and Behavior: The Science of Addiction*, available at https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-abuse-addiction (last visited March 2, 2019).
[4] Id.
[5] *Supra* note 2.
[6] Id.
[7] World Health Organization, *Information Sheet on Opioid Overdose*, World Health Organization (Aug. 2018), available at http://www.who.int/substance_abuse/information-sheet/en/ (last visited March 2, 2019).
[8] National Institute of Neurological Disorders and Stroke, *Pain: Hope through Research*, (last rev. Aug. 8, 2018), available at https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Pain-Hope-Through-Research (last visited March 2, 2019).
[9] Gjermund Henriksen, Frode Willoch; *Brain Imaging of Opioid Receptors in the Central Nervous System,* 131 BRAIN 1171-1196 (2007), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2367693/ (last visited March 2, 2019).
[10] Id.
[11] Id.
[12] Department of Health and Human Services- Substance Abuse and Mental Health Services Administration, *SAMHSA Opioid Overdose Prevention Toolkit: Facts for Community Members* (2013, rev. 2014) 3, available at https://www.integration.samhsa.gov/Opioid_Toolkit_Community_Members.pdf (last visited March 2, 2019).
[13] Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2017 Annual Report*, (Nov. 2018), available at http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2017-Annual-Drug-Report.aspx (last visited March 2, 2019).

- Buprenorphine (Subutex, Suboxone)
- Codeine
- Fentanyl (Duragesic, Fentora)
- Fentanyl Analogs
- Heroin
- Hydrocodone (Vicodin, Lortab, Norco)
- Hydromorphone (Dilaudid, Exalgo)
- Meperidine
- Methadone
- Morphine
- Oxycodone (OxyContin, Percodan, Percocet)
- Oxymorphone
- Tramadol

Opioids are commonly abused, with an estimated 15 million people worldwide suffering from opioid dependence.[14] Opioids can create a euphoric feeling because they affect the regions of the brain involved with pleasure and reward, which can lead to abuse.[15] Continued use of these drugs can lead to the development of tolerance and psychological and physical dependence.[16] This dependence is characterized by a strong desire to take opioids, impaired control over opioid use, persistent opioid use despite harmful consequences, a higher priority given to opioid use than to other activities and obligations, and a physical withdrawal reaction when opioids are discontinued.[17] Nearly 80 percent of people who use heroin first misused prescription opioids.[18]

An overabundance of opioids in the body can lead to a fatal overdose. In addition to their presence in major pain pathways, opioid receptors are also located in the respiratory control centers of the brain.[19] Opioids disrupt the transmission of signals for respiration in the identical manner that they disrupt the transmission of pain signals. This leads to a reduction, and potentially cessation, of an individual's respiration. Oxygen starvation will eventually stop vital organs like the heart, then the brain, and can lead to unconsciousness, coma, and possibly death.[20] Within three to five minutes without oxygen, brain damage starts to occur, soon followed by death.[21] However, this does not occur instantaneously as people will commonly stop breathing slowly, minutes to hours after the drug or drugs were used.[22] An opioid overdose can be identified by a combination of three signs and symptoms referred to as the "opioid overdose triad": pinpoint pupils, unconsciousness, and respiratory depression.[23]

The drug overdose death rate involving opioids has increased by 200% since 2000 and has now become the leading cause of accidental deaths in the United States.[24] Opioid-involved overdoses

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[14] *Supra* note 7.
[15] National Institute on Health, National Institute on Drug Abuse, *Which classes of Prescription Drugs are Commonly Misused?* (rev. Aug. 2016), available at https://www.drugabuse.gov/publications/research-reports/misuse-prescription-drugs/which-classes-prescription-drugs-are-commonly-misused (last visited March 2, 2019).
[16] *Supra* note 9.
[17] *Supra* note 7.
[18] National Institute on Health, National Institute on Drug Abuse, *Prescription Opioids and Heroin*, (rev. Jan. 2018), available at https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use (last visited March 2, 2019).
[19] K.T.S. Pattinson, *Opioids and the Control of Respiration*, BRITISH JOURNAL OF ANAESTHESIA, Volume 100, Issue 6, pp. 747-758, *available at* http://bja.oxfordjournals.org/content/100/6/747.full (last visited March 2, 2019).
[20] Harm Reduction Coalition*, Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects* (Fall 2012), http://harmreduction.org/wp-content/uploads/2012/11/od-manual-final-links.pdf (last visited March 2, 2019).
[21] Id. at 9.
[22] Id. at 9.
[23] *Supra* note 7.
[24] Centers for Disease Control and Prevention, *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014,* Morbidity and Mortality Weekly Report (MMWR) 64(50); 1378-82, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w (last visited March 12, 2018).

accounted for two-thirds of drug overdose deaths from 2015 to 2016.[25] Nationwide, in 2017, there were 47,600 deaths that involved an opioid (licit or illicit), and 17,029 people died from overdoses involving prescription opioids.[26] The most common drugs involved in prescription opioid overdose deaths were methadone, oxycodone, and hydrocodone.[27] In 2017, in Florida, heroin caused 944 deaths, fentanyl and fentanyl analogs caused 3,331 deaths, oxycodone caused 610 deaths, and hydrocodone caused 226 deaths.[28]

Controlled Substance Prescribing for Chronic Pain in Florida

As of January 1, 2012, every physician, podiatrist, or dentist, who prescribes controlled substances in the state to treat chronic nonmalignant pain,[29] must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[30] Before prescribing controlled substances to treat chronic nonmalignant pain, a practitioner must:[31]

- Complete a medical history and a physical examination of the patient which must be documented in the patient's medical record and include:
    - The nature and intensity of the pain;
    - Current and past treatments for pain;
    - Underlying or coexisting diseases or conditions;
    - The effect of the pain on physical and psychological function;
    - A review of previous medical records and diagnostic studies;
    - A history of alcohol and substance abuse; and
    - Documentation of the presence of one or recognized medical indications for the use of a controlled substance.
- Develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment;
- Develop a written individualized treatment plan for each patient stating the objectives that will be used to determine treatment success;
- Discuss the risks and benefits of using controlled substances, including the risks of abuse and addiction, as well as the physical dependence and its consequences with the patient; and
- Enter into a controlled substance agreement with each patient that must be signed by the patient or legal representative and by the prescribing practitioner and include:
    - The number and frequency of prescriptions and refills;
    - A statement outlining expectations for patient's compliance and reasons for which the drug therapy may be discontinued; and
    - An agreement that the patient's chronic nonmalignant pain only be treated by a single treating practitioner unless otherwise authorized and documented in the medical record.

A prescribing practitioner must see a patient being treated with controlled substances for chronic nonmalignant pain at least once every three months, and must maintain detailed medical records relating to such treatment.[32] Patients at special risk for drug abuse or diversion may require consultation with or a referral to an addiction medicine physician or a psychiatrist.[33] The prescribing

[25] Centers for Disease Control and Prevention, *Drug and Opioid-Involved Overdose Deaths – United States, 2013-2017,* Morbidity and Mortality Weekly Report (MMWR) 64(50); 1378-82, available at
[26] Id.
[27] Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data*, (Dec. 19, 2018), available at https://www.cdc.gov/drugoverdose/data/overdose.html (last visited March 2, 2019).
[28] *Supra* note 13.
[29] "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. Section 456.44(1)(e), F.S.
[30] Chapter 2011-141, s. 3, Laws of Fla. (creating s. 456.44, F.S., effective July 1, 2011).
[31] Section 456.44(3), F.S.
[32] Section 456.44(3)(d), F.S.
[33] Section 456.44(3)(e), F.S.

practitioner must immediately refer a patient exhibiting signs or symptoms of substance abuse to a pain management physician, an addiction medicine specialist, or an addiction medicine facility.[34]

Controlled Substance Prescribing for Acute Pain in Florida

Each health care regulatory board whose practitioners prescribe controlled substances must adopt rules establishing guidelines for prescribing controlled substances for acute pain, similar to guidelines established for the prescribing of controlled substances for chronic pain.[35] The Boards of Dentistry, Medicine, Nursing, Optometry, Osteopathic Medicine, and Podiatric Medicine, have adopted rules establishing standards that require, a health care practitioner to:[36]

- Conduct a medical history and physical examination of the patient and document the patient's medical record, including the presence of one or more recognized medical indications for the use of a controlled substance;
- Create and maintain a written treatment plan, including any further diagnostic evaluations or other treatments planned including non-opioid medications and treatments;
- Obtain informed consent and agreement for treatment, including discussing the risks and benefits of using a controlled substance; expected pain intensity, duration, options; and use of pain medications, non-medication therapies, and common side effects;
- Periodically review the treatment plan;
- Refer the patient, as necessary, for additional evaluation and treatment in order to meet treatment goals;
- Maintain accurate and complete medical records; and
- Comply with all controlled substance laws and regulations.

A health care practitioner who fails to follow the guidelines established by the appropriate regulatory board is subject to disciplinary action against his or her license.

Continuing Education on Controlled Substance Prescribing

All health care practitioners who are authorized to prescribe controlled substances must complete a board-approved 2-hour continuing education course, if not already required to complete such a course under his or her practice act.[37] The course must address:

- Current standards on prescribing controlled substances, particularly opiates;
- Alternatives to the current standards on controlled substance prescribing;
- Nonpharmacological therapies;
- Prescribing emergency opioid antagonists; and
- Information on the risks of opioid addiction following all stages of treatment in the management of acute pain.

The course may be taken in a long distance format and must be included in the continuing education required for the biennial renewal of a health care practitioner's license. The department of health may not renew the license of a prescriber who fails to complete this continuing education requirement.

[34] Section 456.44(3)(g), F.S.
[35] Section 456.44(4), F.S.
[36] Rules 64B5-17.0045, 64B8-9.013, 64B9-4.017, 64B13-3.100, 64B15-14.005, 64B18-23.002, F.A.C., respectively.
[37] Section 456.0301, F.S., Pursuant to s. 464.013(3)(b), F.S., an advanced registered nurse practitioner must complete at least 3 hours of continuing education hours on the safe and effective prescribing of controlled substances each biennial renewal cycle. Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C., requires physician assistants who prescribe controlled substances to complete 3 hours of continuing education on the safe and effective prescribing of controlled substance medications.

Advance Directives

An advance directive is a witnessed oral or written statement in which the principal[38] gives instructions or expresses his or her desires regarding any aspect of the principal's health care or health information, including designation of a health care surrogate, a living will, or an anatomical gift.[39] These preferences generally should be honored by the health care team out of respect for patient autonomy.[40]

By law, hospitals, nursing homes, home health agencies, and health management organizations must provide their patients with written information on advance directives and document in the medical record whether an advance directive exists.[41] A health care facility may not require a patient to execute an advance directive and the advance directive must travel with patients as part of the medical record.[42] A health care facility, provider, or other person who carry out health care decisions made in accordance with an advance directive is not subject to criminal prosecution or civil liability, and will not be deemed to have engaged in unprofessional conduct.[43]

Health Care Surrogate

A health care surrogate is a competent adult expressly designated by a principal to make health care decisions on behalf of the principal.[44] The advance directive can specify whether the health care surrogate's authority is exercisable immediately or only upon the principal's incapacity.[45] If the principal's capacity is questionable, the primary or attending physician must evaluate the principal and make a determination.[46] If the finding is that principal lacks capacity, it is noted in the medical record and the health care surrogate's authority becomes exercisable.[47] Unless expressly limited by a principal, a health care surrogate may:[48]

- Make all health care decisions for the principal during the principal's incapacity;
- Consult with appropriate health care providers to provide informed consent, including written consent; provided that such consent reflects the principal's wishes or the principal's best interest;
- Have access to the appropriate health information;
- Apply for public benefits for the principal and have access to the principal's financial information to the extent necessary to make such application;
- Authorize the release of information and medical records to ensure continuity of the patient's health care; and
- Authorize admission, discharge, or transfer of the principal to or from a health care facility.

If the surrogate's authority commences upon the incapacity of the principal, that authority remains in effect until a determination is made that the principal has regained capacity.[49]

If a health care practitioner, health care facility, principal's family, or other interested person may seek judicial intervention if that person believes:[50]

[38] "Principal" means a competent adult executing an advance directive and on whose behalf health care decisions are to be made or health care information is to be received, or both.
[39] Section 765.101(1), F.S.
[40] American Medical Association, *Code of Medical Ethics Opinion 5.2 – Advance Directives*, available at https://www.ama-assn.org/delivering-care/ethics/advance-directives (last visited March 2, 2019).
[41] Section 765.110, F.S.
[42] Id.
[43] Section 765.109, F.S.
[44] Section 765.101(21), F.S.
[45] "Incapacity" means that the patient is mentally or physically unable to communicate a willful and knowing health care decision.
[46] Section 765.204(2), F.S.
[47] Id.
[48] Section 765.205, F.S.
[49] Section 765.204(3), F.S.
[50] Section 765.105, F.S.

- The surrogate's decision is not in accord with the patient's known desires;
- The advance directive is ambiguous, or the patient has changed his or her mind after execution of the advance directive;
- The surrogate was improperly designated or appointed, or the designation of the surrogate is no longer effective or has been revoked;
- The surrogate has failed to discharge duties, or incapacity or illness renders the surrogate or proxy incapable of discharging duties;
- The surrogate has abused his or her powers; or
- The patient has sufficient capacity to make his or her own health care decisions.

Living Wills

A living will expresses a principal's instructions regarding life-prolonging procedures.[51] If a person has a living will but does not have a health care surrogate, a physician may proceed as directed in the living will.[52] Prior to proceeding in accordance to a living will, a health care provider must determine:

- The principal does not have a reasonable medical probability of recovering capacity so that the right could be exercised directly by the principal;
- The principal has a terminal condition, has an end-stage condition, or is in a persistent vegetative state; and
- Any limitations or conditions expressed orally or in a written declaration have been carefully considered and satisfied.

Amendment or Revocation

As long as a person is competent, he or she may revoke or modify the advance directive by:[53]

- A signed, dated writing;
- Physical cancellation or destruction of the advance directive by the principal or at the principal's direction;
- An oral expression of intent to amend or revoke; or
- Subsequently executing an advance directive that is materially different from a previously executed advance directive.

The revocation or amendment becomes effective at the time it is communicated to the health care surrogate, health care practitioner, or health care facility.[54]

Non-Opioid Directives

Several states have enacted legislation creating a voluntary "non-opioid directive".[55] Similar to an advance directive, a non-opioid directive allows patients to express their wishes that they not be given opioids for treatment prior to the need arising. Unlike an advance directive, the non-opioid directive becomes effective while the person is still competent. Typically, the non-opioid directive is a written document that informs a health care provider or health care facility that an individual does not wish to be administered, or offered an opioid as treatment. The individual may revoke the voluntary directive at any time, for any reason, by written or oral means. The laws also generally exempts emergency

[51] Section 765.304(1), F.S.
[52] Id.
[53] Section 765.104, F.S.
[54] Id. An advance directive may also be revoked upon the dissolution of marriage if the former spouse is designated as the surrogate, unless otherwise provided in the advance directive or dissolution of marriage.
[55] *See* ALASKA STAT. s. 13.55.010; LA. REV. STAT. ANN. s. 40:1156.1; 35 PA. CONS. STAT. s. 5203; CONN. GEN STAT. s. 20-14r.; MICH. COMP. LAW s. 333.9145, W. VA. CODE s. 16-54-2; MASS. GEN. LAWS ch. 94, s. 18B; and R.I. GEN. LAWS s. 21-28-3.33.

personnel from liability for administering an opioid, if it is necessary based on the practitioner's professional medical judgment.[56] All of the enacted laws subject health care practitioners to licensure discipline if they fail to honor the non-opioid directive.[57]

Effects of the Proposed Changes

HB 451 requires the Department of Health (DOH) to develop and make available on its website a voluntary non-opioid directive form. The form must inform registrants, who are health care practitioners who prescribe controlled substances for the treatment of chronic nonmalignant pain,[58] that the patient may not be prescribed, ordered, or administered an opioid drug.

Prior to prescribing, ordering, or administering an opioid, a registrant must provide a copy of the voluntary non-opioid directive to any patient that may be prescribed, ordered, or administered an opioid in the course of treatment. The executed voluntary non-opioid directive must be documented in the medical record.

A registrant who refuses to prescribe, order, or administer an opioid in compliance with a voluntary non-opioid directive may not be held liable, civilly or criminally, or deemed to have violated the standard of care for such action if the health care practitioner exercised reasonable care. However, if a registrant fails to comply with a voluntary non-opioid directive or the revocation of such, he or she may be subject to licensure discipline.

The bill authorizes an individual to appoint a guardian or health care surrogate on the voluntary non-opioid directive who has the authority to revoke the form in writing or orally, at any time, for any reason. The bill provides civil and criminal immunity to any such guardian or health care surrogate who, acting in good faith, revokes the voluntary non-opioid directive.

The bill also establishes a presumption of validity for any electronically-transmitted opioid prescription, and authorizes a pharmacist to dispense the opioid even if the patient has executed a voluntary non-opioid directive. For a pharmacist who exercises reasonable care, the pharmacist is immune from civil liability, criminal prosecution, and is deemed to not have violated the standard of care for dispensing an opioid in contradiction to the voluntary non-opioid directive.

The bill also provides that a registrant employed by a hospital emergency department, acting as the patient's physician or the emergency medical services director, who prescribes, orders, or administers an opioid to a patient who has a voluntary non-opioid directive may not be held liable, civilly or criminally, or deemed to have violated the standard of care for such action if the registrant reasonably believes an opioid is necessary and had no knowledge of the voluntary non-opioid directive.

The bill provides an effective date of July 1, 2019.

B. SECTION DIRECTORY:

Section 1: Amends s. 456.44, F.S., relating to controlled substance prescribing.
Section 2: Provides an effective date of July 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

[56] Id.
[57] Id.
[58] Registrants is defined in s. 456.44(1)(h), F.S. "Chronic nonmalignant pain" is pain unrelated to cancer which persist beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery (s. 456.44(1)(f), F.S.)

1. Revenues:

   None.

2. Expenditures:

   DOH will incur a non-recurring, insignificant fiscal impact related to development of the voluntary non-opioid directive form, updating the departmental website, and rulemaking, which current resources are adequate to absorb.[59]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

B. RULE-MAKING AUTHORITY:

DOH has sufficient rule-making authority to implement the bill's provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill limits the applicability of the non-opioid directives to only those health care practitioners who prescribe controlled substances for the treatment of chronic malignant pain, rather than to all controlled substance prescribers.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[59] Department of Health, *2019 Agency Analysis for House Bill 451,* (Jan. 22, 2019), (on file with the Health Quality Subcommittee).